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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,823	06/25/2003	Olivier De Lacharriere	016800-515	1993

7590 05/31/2007  
BURNS, DOANE, SWECKER & MATHIS, L.L.P.  
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Alexandria, VA 22313-1404

EXAMINER
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DUTT, ADITI

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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05/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,823	<b>Applicant(s)</b> LACHARRIERE ET AL.	
	<b>Examiner</b> Aditi Dutt	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25,27-54 and 56-67 is/are pending in the application.
- 4a) Of the above claim(s) 64-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25,27-54 and 56-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25,27-54 and 56-67 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. The amendment filed on 14 March 2007 has been entered into the record and has been fully considered. Claims 1-3, 16, 17, 28, 33, 37, 53, are amended. Claims 26, 55, are canceled. Claims 39-40, 45-46 and 64-67 are withdrawn from consideration, by the Applicant.
2. Claims 1-25, 27-38, 41-44, 47-54, 56-63, directed to a non-therapeutic method of evaluating level of skin neurosensitivity and identifying persons having sensitive skin are under examination in the instant application.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on 14 March 2007, have been fully considered. New grounds of objection and rejection are as follows:

### ***Response to Amendment***

#### **Withdrawn objections and/or rejections**

5. Upon consideration of the Applicant's amendment, all claim objections and rejections, not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (14 March 2007).

Claim rejections/objections maintained/new grounds of rejection

35 U.S.C. 112-first paragraph- Written Description.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejections of claims 1-38, 41-44, 47-63 are applied to the amended claims (1-25, 27-38, 41-44, 47-54, 56-63), for reasons of record in the Office Action dated 14 September 2006.
7. Applicants disagree with the Office's rejection, because the claimed peripheral nervous stimulants naturally possess the biological activity of peripheral nervous stimulation. The claims also recite other biological activities such as induction of unattractive sensation, which in turn can induce the release of CGRP and substance P, after topical application. Applicants further assert that peripheral nervous stimulants, for example lactic acid, glycolic acid, capsaicin and its derivatives, ethanol or mustard oil, each have specific structures. Applicants have amended the claims to recite the various types of unattractive sensations. Finally, Applicants argue that specific examples of cosmetics and vehicles are provided in the specification, which are also known in the art. Based on the above explanation of the structures and functions, Applicants believe that the specification provides sufficient description of the claimed invention, thus the rejection should be withdrawn.

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8. Applicant's arguments have been fully considered but have not been found to be persuasive. Although, the species of peripheral nervous system stimulants, cosmetics and vehicles are listed, the specification does not teach a definitive structure function relationship of the above mentioned claimed genus of stimulants that can be correlated with the genus of unattractive sensations produced by them. Mere knowledge of the structure does not provide adequate distinguishing characteristics of the entire genus of peripheral nervous stimulants necessary for detecting neurosensitivity. Additionally, as mentioned in the specification, the function of unattractive skin sensation can be produced by a host of other unrelated factors such as the environment, emotional and physiological changes, dietary and other topical applications, giving rise to a variety of subjective and objective responses to different stimuli in different subjects.

As stated in the previous Office Action,

With the exception of capsaicin as the peripheral nervous system stimulant, the skilled artisan cannot envision the peripheral nervous stimulants, cosmetics, vehicles and unattractive sensations of the encompassed methods and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of detecting skin neurosensitivity.

Therefore, methods of using a specific cosmetic or capsaicin in a specific vehicle, and a specific unattractive sensation to detect skin neurosensitivity, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The rejection of claims 1-17, 20-27, 28-38, 41-44 and 48-55, as unpatentable over Robinson and Perkins (Contact Dermatitis 45: 205-213, 2001) are applied to the amended claim 1-17, 20-25, 27, 28-38, 41-44, 48-54 for reasons of record in the Office Action dated 14 September 2006.
10. Applicant argues that the current application describes methods for evaluating the skin sensitivity of individuals belonging to the sensitive skin population. Applicant further argues that the data provided by the Robinson et al is based on self-assessed sensation, which does not correlate with the cutaneous tests performed. Furthermore, Applicant believes that Robinson et al does not suggest low concentration capsaicin, as recited in the instant claims, which is important for cosmetic diagnosis to select individuals having more sensitive skin. Thus, the Applicant contends that the present claims are not obvious over Robinson et al, therefore, the rejection should be withdrawn.
11. Applicant's arguments have been fully considered but have not been found to be persuasive. Robinson et al. uses the labeled magnitude

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(LM) scale for quantifying subjective sensory irritation responses, that correlate with the actual responses observed after different doses of capsaicin challenge. Although Robinson et al. do not teach the instant doses of the stimulant, optimization within prior art conditions or through routine experimentation is obvious to one skilled in the art. As stated in the previous Office Action,

It would have been, therefore, obvious to the person of ordinary skill in the art at the time the claimed invention was made to determine the optimal ranges of capsaicin and alcohol content in the solution of the skin neurosensitivity testing method as taught by Robinson. The person of ordinary skill in the art would have been motivated to perform such tests on sensitive skin to assess the response to various products and chemicals (Robinson).

Thus, claims 1-17, 20-25, 27, 28-38, 41-44, 48-54 as a whole was *prima facie* obvious over the teachings of Robinson et al, and stay rejected.

12. The rejection of claims 1-17, 20-27, 28-38, 41-44 and 48-55, as unpatentable over Robinson and Perkins (Contact Dermatitis 45: 205-213, 2001), in view of Hahn and Thueson (U.S. Patent No. 6,139,850, issued on 31 October 2000), are applied to the amended claim 1-17, 20-25, 27, 28-38, 41-44, 48-54 for reasons of record in the Office Action dated 14 September 2006.

13. Applicant argues that, as Hahn et al. do not rectify the deficiencies of Robinson et al., the claims are not obvious over the combination of

Robinson et al. and Hahn et al., and, therefore, the rejection should be withdrawn.

14. Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above the claimed invention is obvious over the teachings of Robinson et al alone, and, thus is also rejected as being obvious over Hahn et al. in combination with Robinson et al.

### ***New Rejection***

#### ***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438,



164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

16. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
17. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
18. Claims 3, 5-9 and 16, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 57 of copending Application No. 10/674,491. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the evaluation of skin or cutaneous neurosensitivity, comprising, (i) applying a substance or a composition comprising a stimulant of the peripheral nervous system and a physiologically acceptable vehicle, to a skin area or cutaneous zone; (ii) recording a dysesthetic or unattractive sensation detected by the individual; (iii) repeating steps (i) and (ii) using a higher concentration of the stimulant until the individual detects an unattractive/dysesthetic sensation, or until the maximum concentration of the stimulant is applied;

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(iv) deducing the skin/cutaneous neurosensitivity of the individual from the last concentration applied.

19. The only differences between claim 57 of the '491 application and claims 3, 5-9 and 16 of the instant application is that claim 57 of the '491 are as follows: (I) Claim 57 of the '491 application does not recite concentration range of the stimulant, while claims 3, 5-9 and 16 of the instant application recite the ranges and the factor of increase of the stimulant. (II) Claim 57 describes the application of the substance using an applicator, while claims 3, 5-9 and 16 of the instant application do not recite an applicator. However, this limitation is inherent, because stimulating agent requires application to the skin, which would obviously be performed using standard applicators. (III) Claim 57 does not describe the dysesthetic sensation types, while claims 3, 5-9 and 16, lists the unattractive sensations detected by the individual (e.g. itching, stinging, etc.). This limitation is also inherent to peripheral nervous system stimulants such as capsaicin, one of stimulating agents stated in the specification of the '491 application (page 2, para 0012).

Additionally, optimization within prior art conditions or through routine experimentation is obvious to one skilled in the art. As stated in MPEP

2144.05:

"The differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[V]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." "The normal

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desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages". *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382; *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.).

20. Therefore, the instant claims 3, 5-9 and 16, are not patentably distinct over claim 57 of the '491 application.
21. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

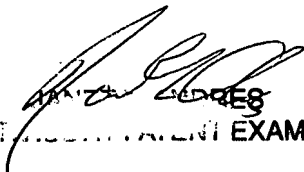
### **Conclusion**

22. No claims are allowed.
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.
24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is

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available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD  
22 May 2007

  
SUPERVISOR EXAMINER